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10/542,577	07/19/2005	Takanori Uchida	UCHIDA=9	6886
1444	7590	05/12/2011	EXAMINER	
Browdy and Neimark, PLLC 1625 K Street, N.W. Suite 1100 Washington, DC 20006			KIM, TAEYOON	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,577	Applicant(s) UCHIDA ET AL.	
	Examiner TAEYOON KIM	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 17-21, 24-29, 32-34, 36-38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17-21, 24-29, 32-34, 36-38 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/3/11</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and response filed on 3/10/2011 has been received and entered into the case.

Claims 1-13, 15, 16, 22, 23, 30, 31, 35, 39 and 40 are canceled, and claims 14, 17-21, 24-29, 32-34, 36-38 and 41 are pending and have been considered on the merits. All arguments have been fully considered.

The claim objection has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. § 112 has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 17-21, 24-29, 32-34, 36-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 17-20 and 41 disclose a new limitation directed to the method being capable of preventing recurrent bleeding, projectile bleeding and exudative bleeding with a single hemostatic treatment. It is understood that the instant method claims are directed to the steps of making the bioabsorbable synthetic nonwoven fabric holding thrombin and fibrinogen. The method steps would produce a hemostatic material. None of steps is directed to any step of using the product. However, the newly introduced limitation is directed to the method steps of making the hemostatic material and claims that the method steps of making such material would

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necessarily prevent various types of bleeding problems. It is more likely that the bioabsorbable material is capable of preventing bleeding. Clarification is required.

The term “preventing” in the instant claims does not clearly point out the scope of the term intended in the claimed invention. It is understood that the term “preventing” would encompass broader scope than the intended scope of hemostatic treatment. It is understood that the hemostatic material prepared by the claimed steps would be used after the onset of bleeding, and thus, it is more likely directing to the stopping of bleeding or “preventing” further bleeding, rather than preventing any bleeding including applying the material prior to any bleeding. The scope of the term "preventing" is much broader than the purpose of hemostatic treatment. Thus, it is vague what the scope encompassed by the term “preventing” is. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 17-21, 24-29, 32-34, 36-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current application generically claims any recurrent bleeding, projectile bleeding or exudative bleeding by using the hemostatic material of the claims, however the specification does not contain an adequate description for the entire scope of this limitation and thus the

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claims. The claims are not limited to a particular species just generically any bleeding including recurrent, projectile or exudative bleeding. It is noted that while the new limitation is directed to recurrent bleeding, projectile bleeding AND exudative bleeding, it is understood that this limitation is supposed to be a selective listing of species according to the specification, and thus, interpreted as “recurrent bleeding, projectile bleeding OR exudative bleeding”.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The claims are essentially of limitless breadth. It is implied that so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim, one can thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166

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The specification discloses examples of a single hemostatic treatment using the product produced by the claimed method steps would stop the projectile or exudative bleeding and showed that a sheet holding thrombin followed by lyophilization and spraying fibrinogen solution immediately prior to the use would thoroughly cease the projectile bleeding with a single hemostatic treatment (p.11, lines 9-15; p.12, lines 16-19).

However, the example shown in the specification is under only one type of projectile bleeding generated by sticking 21G needle to the abdominal aorta of a rabbit. It does not provide sufficient written description to the entire scope of bleeding conditions (e.g. different size, location, etc.) that the product produced by the claimed method would unconditionally cease any type of projectile bleeding with a single treatment.

Every species in a genus need not be described in order that a genus meets the written description requirement. See *Utter*, 845 F.2d at 998- 99,6 USPQ2d at 1714 ("A specification may, within the meaning of §112, first paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") In claims to a species from a genus, however, a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed species of the genus from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute

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requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369,372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally thought to exist, in the absence of knowledge as to what that material consists of, is not a description of that entire material.

Claims 14, 17-20, 36-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The instant claims are directed to a method of preparing a bioabsorbable synthetic nonwoven fabric made of PGA holding thrombin and fibrinogen wherein the thrombin and fibrinogen being applied sequentially onto the fabric immediately (claims 14, 17-20 and 41), and

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the bioabsorbable hemostatic synthetic nonwoven fabric having thrombin added immediately prior to use and fibrinogen added immediately prior to use (claims 36-38).

It is noted that while the new limitation is directed to recurrent bleeding, projectile bleeding AND exudative bleeding, it is understood that this limitation is supposed to be a selective listing of species according to the specification, and thus, interpreted as “recurrent bleeding, projectile bleeding OR exudative bleeding”.

The specification discloses three hemostatic materials (Group I, II and III) (p.11-12). According to the specification, Group 2 material is prepared by spraying a solution containing thrombin and a solution containing thrombin immediately prior to the use, and thus, Group 2 is the same embodiment as the instantly claimed invention. According to the specification, however, Group 2 material was not capable of ceasing the projectile bleeding with a single treatment (see Table 1; p.12, lines 19-24).

Therefore, the specification does not provide the enabling embodiment for the preventing projectile bleeding with a single hemostatic treatment that the claimed method and product produced by applying fibrinogen and thrombin sequentially onto the nonwoven synthetic fabric of PGA prior to use.

Claims 21, 24-29 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the condition when the ingredients listed in the composition (kit) is prepared under the steps disclosed as “Group 1” in the specification, does not reasonably provide enablement for any other condition including “Group 2” as in the specification, for example. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The instant claims are directed to a kit comprising nonwoven needle-punched PGA fabric holding thrombin, and a container comprising fibrinogen. The new limitation merely claims that when both thrombin and fibrinogen are held onto the fabric can prevent recurrent bleeding, projectile bleeding and exudative bleeding with a single hemostatic treatment.

As discussed above, the specification discloses a single embodiment which was capable of ceasing projectile bleeding is Group 1 material whereas Group 2 material, which also meets the limitation of the instant claims (i.e. holding both thrombin and fibrinogen), is incapable of ceasing projectile bleeding with a single treatment (Table 1). Thus, while the holding of thrombin and fibrinogen onto the fabric mediated by the process steps for Group 1 according to the specification would allow the ceasing of projectile or exudative bleeding with a single treatment for the wound or bleeding prepared by needle-puncture with 21G needle on a rabbit abdominal aorta, the material prepared by the steps of Group 2 material was only capable of ceasing exudative bleeding with a single treatment but not projectile bleeding.

Thus, it is concluded that the specification fails to provide enablement to a person of ordinary skill in the art to make and/or use the claimed invention commensurate with the entire scope of the claims without undue experimentation.

It is also noted that while Group 1 material could cease the projectile bleeding as well as exudative bleeding, however, as discussed above in written description rejection, this is limited to the single embodiment directed to a single bleeding condition generated by a specific puncture or needle poking onto the rabbit abdominal aorta. This is not sufficient to show whether the

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claimed method of preparing and the claimed product would be capable of ceasing ANY types of bleeding with a single treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17-21, 24-29, 32-34, 36-38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugitachi et al. (of record) in view of Greenawalt et al. (of record) and Gunze (JP 63095041; same as the English translation of JP1993-018527 submitted on 11/27/2007; Abstract only) for the reason set forth in the previous OA mailed on 9/10/2010.

With regard to the new limitation directed to the intended result of using the claimed product, the references do not particularly teach the limitation. However, the method steps of Sugitachi et al. in view of Greenawalt et al. and Gunze are considered the same as the claimed method steps, and thus, the resulting product would be the same, it is expected that the property of the produced product by the process taught by Sugitachi et al. in view of Greenawalt et al. and Gunze would be the same as the claimed invention.

In the response, Applicant alleged that Greenawalt is not relevant to the objective of Sugitachi because the invention of Sugitachi is about the fixation of Factor XIII to a wound

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healing material, and thrombin can be used together with Factor XIII because it further promotes the formation of non-stabilized fibrin at a wound site, and the purpose of thrombin taught by Sugitachi is merely an agent for assisting the activity of Factor XIII.

Applicant asserted, therefore, that there is no reason to even try to add both thrombin and fibrinogen to the same substrate of Sugitachi, and the proposed combination would not have been obvious at the time the present invention was made.

Applicant's arguments have been fully considered but found not persuasive.

The purpose of Sugitachi's material and the process steps of making one is to treat wound and thus encompasses hemostatic application. Factor XIII of the substrate is for inducing or promoting the formation of stabilized fibrin at a wound site. It is extremely well known in the art that the formation of fibrin clots require thrombin which activates fibrinogen, and the addition of thrombin onto the substrate (e.g. PGA) along with Factor XIII is intended for the activation of endogenous fibrinogen in the blood of the patients. Furthermore, it is also known in the art that thrombin and fibrinogen can be applied exogenously to form fibrin clot on the wound sites as taught by Greenawalt. Thus, one skilled in the art would certainly understand the purpose of thrombin taught by Sugitachi, and also recognize the addition of fibrinogen exogenously would promote fibrin clot beneficial to wound healing. Therefore, the combination of fibrinogen to the Sugitachi's substrate comprising Factor XIII and thrombin is obvious.

Applicant argued that the person of ordinary skill in the art cannot be expected to try a large number of alternative substrates, none of which is said to be any better than any of the others, in the hope of finding one which possesses improved properties. The Examiner respectfully disagrees with the applicant's argument.

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It appears that applicant emphasizes the use of non-woven fabric of PGA which is needle-punched and elastic provides improved properties to the hemostatic application of thrombin and fibrinogen to the bleeding site. There is no evidence provided whether the particular fabric provides such "improved" property. Rather the specification only compares between PGA based material with thrombin and fibrinogen to collagen based material. However, this cannot be considered as unexpected and surprising results since Greenawalt et al. teach that collagen based carrier holding thrombin and fibrinogen had difficulties in achieving optimum timing for the fixing procedure have been reported using the collagen based hemostatic material resulting in inconsistent attachment and stability of the active components onto the collagen carrier, and the penetration of the active components beyond the surface of the collagen carrier is not possible, thereby limiting the concentration of blood-clotting components (thrombin and fibrinogen) (col. 1, line 61 through col. 2, line 19). Thus, Greenawalt et al. recognize drawbacks of using collagen carriers for blood clotting components, and Greenawalt et al. teach a bioabsorbable polymer such as PGA would provide better outcome compared to collagen based material such as TachoComb or Avitene (Example 6 and 16). Thus, it is known at the time of the claimed invention was made that PGA provides better results in a hemostatic application compared to collagen based hemostatic material. Thus, one skilled in the art would know the fact that PGA based hemostatic material is better than collagen based hemostatic material based on the teaching of Greenawalt et al.

Lastly the use of PGA fabric known as Neoveil is well known in the art according to Gunze, and the use of Neoveil for the hemostatic application is thus obvious.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 11/941,779.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications disclose a method of preparing nonwoven fabric comprising PGA holding thrombin by immersing the fabric into a saline or buffer solution containing thrombin, followed by lyophilizing the fabric. Although the claims of '779 application do not particularly teach a step of adding fibrinogen immediately prior to use of the thrombin-PGA fabric, it would have been obvious to a person of ordinary skill in the art to use fibrinogen because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin as a hemostatic purpose. Thus, a person of ordinary skill in the art would recognize that the method of '779 is

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directed to the making of intermediate product of non-woven fabric holding thrombin, which can be used for the final hemostatic materials in combination with fibrinogen. Therefore, it is considered that the claims of '779 application render the claim of instant application obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TAEYOON KIM** whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651